510(k) SUMMARY

JAN 2 5 2007

Date 19 October 2005

Owner Baxter Healthcare Corporation

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Device name Ipump™ Pain Management System

Common name External Infusion Pump

Classification name Infusion Pump (21 CFR 880.5725, Product Code 80 FRN)

Predicate Device Ipump™ Pain Management System, K993387 cleared on 01 November 1999

Device Description

The Ipump™ Pain Management System is an external infusion pump offering three different modalities for the delivery of medications to a patient. The modalities include Patient Controlled Analgesia (PCA) mode, PCA plus basal (continuous) mode, and continuous mode.

PCA mode delivers a bolus of a medication at a fixed rate of 90 mL/hr at patient-controlled time intervals by pressing the PCA button. *PCA plus basal (continuous) mode* delivers medication at 90 mL/hr during patient-controlled time intervals in conjunction with the desired basal delivery of between 0.1 mL/hr and 19.9 mL/hr between PCA doses. In *continuous mode*, the pump delivers medication continuously at a rate adjustable between 0.1 mL/hr and 90.0 mL/hr.

The Ipump operates using a linear peristaltic pumping mechanism and a DC motor with either a 9 volt alkaline battery or an AC adapter power source. The pump's features include an air sensor, an upstream occlusion detector and a down stream occlusion detector. The disposables for the Ipump™ Pain Management System consist of numerous custom tubing sets and flexible non-vented reservoir bags of up to 500 ml.

Statement of Intended Use

The Ipump™ Pain Management System is indicated for the controlled delivery (continuous, intermittent, and continuous plus intermittent) of analgesic, sedative, and anesthetic solutions through clinically acceptable routes of administration including intravenous, subcutaneous, and epidural, and for regional (local) analgesia applications.

Technological Characteristics

The subject and predicate devices are similar in operating principle, material composition, energy sources, environmental specifications, performance, dimensional specifications and packaging. A summary of the technological characteristics for the subject and predicate devices follows in Table 1.

Table 1. Ipump™ Pain Management System Technological Characteristics Comparison

Functional Features	Predicate Ipump	Subject Ipump
Power Sources		
9 volt battery	included	included
100-120 VAC, 60 Hz 220-240 VAC, 50 Hz	included	included
Key Features:	included	included
Air sensor	included	included
Preventative maintenance alert	included	included
Multilanguage interface	included	included
Detailed history display and printout capability	included	included
Ability to transfer data to another Ipump	included	included
Upstream and downstream occlusion detectors	included	included
Programmable limits for PCA doses	included	included
Record Management:		
Tracking of programming, time and history	included	included
Data retained in memory after pump is off	included	included
Real time clock	included	included
Security		
Key only	included	included
Code only	included	included
Key plus code	included	included
Setting up of the Pump		
PCA cord	included	included
May be IV pole mounted	included	included
Pumping Mechanism:		
DC motor	included	included
Linear peristaltic motion	included	included
Display Technology		
Liquid crystal display	included	included
Keypad		
Keypad with action keys	included	included

The technological characteristics of the subject Ipump™ Pain Management System do not raise new questions of safety or effectiveness.

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Assessment of Non-clinical Data

A summary and assessment of the non-clinical performance data relied upon to support substantial equivalence follows:

Electrical safety: Ipump was evaluated against the applicable requirements contained within IEC 60601-1 with successful results.

Electromagnetic Compatibility (EMC): The Ipump characteristics were evaluated against the applicable requirements contained within IEC 60601-1-2 second edition, augmented by the IEC 60601-2-24 clause 36 requirements, with sucessful results.

The Ipump performance during environmental testing, such as the operating and storage conditions, as well as shock and vibration tests has been determined to meet its acceptance criteria.

The performance characteristics of the Ipump were evaluated against the applicable requirements contained within IEC 60601-2-24 with successful results.

Software testing was performed at the system level, unit level and integration level to demonstrate that the design changes satisfy the various Ipump™ Pain Management System requirements. Regression testing was performed to demonstrate that the design changes have not adversely affected those parts of the system not changed. The data recorded from the software testing has been determined to meet its acceptance criteria.

A comparison of the predicate device with the subject Ipump shows that the same components come into direct and indirect contact with the patient. These components are processed by the same manufacturing methods, and are of the same patient contact duration and material type. Biocompatibility requirements are therefore satisfied.

The data supports the subject Ipump has shown equivalent characteristics in its electrical safety, EMC, environmental, performance, software and biocompatibility testing.

Conclusion

Baxter Healthcare Corporation concludes that the results obtained during non-clinical performance testing for Ipump™ Pain Management System supports a determination of substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Baxter Healthcare Corporation
C/O Ms. Barbara K. Barbeau
Senior Director, Global Regulatory Affairs
Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, Illinois 60085-6730

JAN 25 2007

Re: K052973
Trade/Device Name: Ipump™ Pain Management System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 13, 2006
Received: November 15, 2006

Dear Ms. Barbeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052973

Device Name: Ipump™ Pain Management System

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Prescription Use X **AND / OR** **Over-the-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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